



2025/1879

17.9.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/1879

of 16 September 2025

renewing the approval of the low-risk active substance rape seed oil in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾ and in particular Article 20(1) in conjunction with Article 22(1) thereof,

Whereas:

- (1) Commission Directive 2008/127/EC ⁽²⁾ included rape seed oil as an active substance in Annex I to Council Directive 91/414/EEC ⁽³⁾.
- (2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽⁴⁾.
- (3) The approval of the active substance rape seed oil, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 March 2026.
- (4) An application for the renewal of the approval of the active substance rape seed oil was submitted to the Netherlands, the rapporteur Member State, and Finland, the co-rapporteur Member State, in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ⁽⁵⁾ and within the time period provided for in that Article. The applicant submitted the supplementary dossiers to the rapporteur Member State, the co-rapporteur Member State, the Commission and the European Food Safety Authority ('Authority'). The rapporteur Member State considered the application admissible.
- (5) The rapporteur Member State prepared a draft renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the Authority and the Commission on 24 March 2020. In its draft renewal assessment report, the rapporteur Member State proposed to renew the approval of rape seed oil.
- (6) The Authority made the supplementary summary dossier available to the public. The Authority also communicated the draft renewal assessment report to the applicant and to the Member States for comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/1107/oj>.

⁽²⁾ Commission Directive 2008/127/EC of 18 December 2008 amending Council Directive 91/414/EEC to include several active substances (OJ L 344, 20.12.2008, p. 89, ELI: <http://data.europa.eu/eli/dir/2008/127/oj>).

⁽³⁾ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1, ELI: <http://data.europa.eu/eli/dir/1991/414/oj>).

⁽⁴⁾ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2011/540/oj).

⁽⁵⁾ Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26, ELI: http://data.europa.eu/eli/reg_impl/2012/844/oj).

- (7) On 4 April 2022, the Authority communicated to the Commission its conclusion ⁽⁶⁾ indicating that rape seed oil is unlikely to have endocrine disrupting properties and that, taking into account the approval criteria laid down in Annex II to Regulation (EC) No 1107/2009, plant protection products containing rape seed oil can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (8) The Commission presented a renewal report and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 13 October 2022 and 9 December 2022, respectively.
- (9) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 14(1), third subparagraph, of Implementing Regulation (EU) No 844/2012, on the renewal report. The applicant submitted its comments, which have been carefully examined and taken into consideration.
- (10) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance rape seed oil that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (11) Although the risk assessment for the renewal of the approval of the active substance rape seed oil is based on a limited number of representative uses, this does not restrict the uses for which plant protection products containing rape seed oil may be authorised.
- (12) The Commission further considers that rape seed oil is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. Rape seed oil is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009. Following the assessment of the substance by the Rapporteur Member State and the Authority, and considering its intended uses, it is expected that plant protection products containing rape seed oil will pose only a low risk to human and animal health and the environment.
- (13) It is therefore appropriate to renew the approval of rape seed oil as a low-risk active substance.
- (14) In accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge and the outcome of the risk assessment, it is, however, necessary to provide for certain conditions.
- (15) Implementing Regulation (EU) No 540/2011 should be amended accordingly.
- (16) Commission Implementing Regulation (EU) 2024/2221 ⁽⁷⁾ extended the expiry date of rape seed oil to 31 March 2026 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. However, given that a decision on renewal has been taken ahead of that extended expiry date, this Regulation should apply earlier than that date.
- (17) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the approval of the active substance

The approval of the active substance rape seed oil, as specified in Annex I to this Regulation, is renewed, subject to the conditions laid down in that Annex.

⁽⁶⁾ EFSA (European Food Safety Authority), 2022. Conclusion on the peer review of the pesticide risk assessment of the active substance rape seed oil; *EFSA Journal* 2022;20(5):7305, doi:10.2903/j.efsa.2022.7305.

⁽⁷⁾ Commission Implementing Regulation (EU) 2024/2221 of 6 September 2024 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances acequinocyl, aluminium silicate, emamectin, fatty acids C7 to C20, pendimethalin, plant oils / rape seed oil and triclopyr (OJ L, 2024/2221, 9.9.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/2221/oj).

*Article 2***Amendment to Implementing Regulation (EU) No 540/2011**

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

*Article 3***Entry into force and date of application**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 November 2025.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 16 September 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
Rape seed oil CAS No: 8002-13-9 (Rape seed oil) 93165-31-2 (Rape seed oil – low erucic acid) CIPAC No: Not available	Rape seed oil	The purity complies with the European Pharmacopeia 7.0 and Deutscher Arzneimittel-Codex 1986, 6. Erg. 1994 and ph. Eur. 5, 2005. The active substance is a mixture of triglycerides of fatty acids and the mode of action is mechanical rather than chemical: 100 % of the technical active substance is considered as an active substance. The specifications are based on the composition as fatty acids and some physical and chemical parameters. The impurity erucic acid shall not exceed 2 %.	1 November 2025	31 October 2040	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on rape seed oil, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of aquatic organisms, honey bees, and non-target arthropods. Conditions of use shall include risk mitigation measures, where appropriate.

⁽¹⁾ Further details on the identity and specification of the active substance are provided in the renewal report.

ANNEX II

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

- (1) in Part A, entry 242 on rape seed oil is deleted;
- (2) in Part D, the following entry is added:

No	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
'54	Rape seed oil CAS No: 8002-13-9 (Rape seed oil) 93165-31-2 (Rape seed oil – low erucic acid) CIPAC No: Not available	Rape seed oil	The purity complies with the European Pharmacopeia 7.0 and Deutscher Arzneimittel-Codex 1986, 6. Erg. 1994 and ph. Eur. 5, 2005. The active substance is a mixture of triglycerides of fatty acids and the mode of action is mechanical rather than chemical: 100 % of the technical active substance is considered as an active substance. The specifications are based on the composition as fatty acids and some physical and chemical parameters. The impurity erucic acid shall not exceed 2 %.	1 November 2025	31 October 2040	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on rape seed oil, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of aquatic organisms, honey bees, and non-target arthropods. Conditions of use shall include risk mitigation measures, where appropriate.'

⁽¹⁾ Further details on the identity and specification of the active substance are provided in the renewal report.